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10/822,138	04/12/2004	Kenneth F. Binmoeller	026923-000200US	1173

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EXAMINER

MASHACK, MARK F

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3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,138	Applicant(s) BINMOELLER ET AL.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48,50-53,56 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48,50-53,56 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/20/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 5/21/2010. Claims 48 and 50-53, 55, 57-59 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 48, 50-53, 55, 57-58** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim limitation "applying proximal tension... prior to deployment of the proximal anchor".

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 48, 50-53, 55, 57-58** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. **Claim 48** recites the limitation "deployment of the proximal anchor". There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

6. Applicant's arguments filed 5/21/2010 have been fully considered but they are not persuasive.

7. Applicant argues that "Examiner cannot maintain the argument that deployment of the Evard anchors would somehow inherently pull the distal anchor proximally against the distal side of the distal tissue layer, since there never is tension applied to the apparatus when it is deployed with a push-rod". Examiner disagrees. **Evard** discloses that "the apparatus may be self expanding... such that the radial expansion of the engagement members will occur when surrounding constraint (e.g., constraint of a surrounding catheter wall) has been removed from the apparatus" and further discloses "after the catheter 100a has been advanced to the desired location, the sheath 104 may then be retracted (or alternatively the inner member 102 may be advanced) thereby removing the surrounding constraint from the connector apparatus 10" (Page 41-42). When the anchors are expanding, the distal ends inherently are pulled against the wall.

8. Applicant argues that "Suyker would not apply proximal tension prior to deployment of the proximal anchor". Examiner disagrees. Examiner considers the "deployment of the proximal anchor" is not performed until the proximal anchor is completely expanding. Tension is applied prior to the proximal anchor being completely expanded.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. **Claims 48 and 50-53, 55, 57-58** are rejected under 35 U.S.C. 102(b) as being anticipated by **Evard et al. ("Evard" WO 97/27898)**.

Evard discloses a method of anchoring a tissue to a luminal structure by forming a vascular anastomosis (Page 1, Lines 15-19) comprising the steps of: positioning an apparatus (Page 3, Line 14, - Page 4, Line 8) to a wall of a luminal structure; manually advancing an assembly member **10** comprising a central member **38a, 84, 94** through a tissue penetration; deploying first and second anchors from the central member engaging the tissue on the distal and proximal side **20, 92** wherein the radius of the central member expands (Page 3, Lines 14-22) to provide a lumen (FIG 10) through the tissue. **Regarding Claim 50 and 52**, the deploying of the first and second anchors comprises self-expansion (Page 3, Lines 33-37). **Regarding Claim 51**, the anchors comprise a mesh (Page 30, Lines 16-28). **Regarding Claim 53 and 55**, **Evard** discloses that "the present invention is implanted or installed within openings formed in

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adjacent blood vessels” (Column 15, Lines 22-32). **Regarding Claim 57 and 58**, “the leading edge of the apparatus may be a sharpened cutting edge or may be otherwise adapted to cut or sever tissue... to form such openings or passageway, or to enlarge, customize, model or otherwise alter the tissue with which it comes into contact” (Column 6, Lines 3-11). Examiner contends that since the apparatus “enlarge[s]” an opening, the apparatus requires a “pre-formed opening” and it further “opens a tissue penetration”.

Evard discloses that “the apparatus may be self expanding... such that the radial expansion of the engagement members will occur when surrounding constraint (e.g., constraint of a surrounding catheter wall) has been removed from the apparatus” and further discloses “after the catheter 100a has been advanced to the desired location, the sheath 104 may then be retracted (or alternatively the inner member 102 may be advanced) thereby removing the surrounding constraint from the connector apparatus 10” (Page 41-42). When the anchors are expanding, the distal ends inherently are pulled against the wall.

Regarding the newly amended claims, Examiner asserts that the “deployment of the proximal anchor” is not completely performed until the proximal anchors are completely expanded. The sheath is retracted prior to the “deployment of the proximal anchor”.

11. **Claims 48 and 59** are rejected under 35 U.S.C. 102(e) as being anticipated by **Suyker et al. (“Suyker” US 6,966,917)**.

Suyker discloses a method of anchoring proximal and distal tissue layers (Column 1, Lines 20-21) comprising position an apparatus next to a wall of the proximal tissue layer; manually advancing the apparatus to penetrate an assembly including a hollow cylindrical central member **3, 4** having a distal and proximal anchors **5, 6**; deploying the distal anchor from the central member such that said distal anchor expands to engage a distal side of the distal tissue layer; applying proximal tension to the apparatus to pull the distal anchor proximally against the distal side of the distal tissue layer while the proximal anchor is deployed; **Regarding Claim 59**, a pusher **23** is provided on a proximal side of the assembly to applying a compressive force to expand the radius of the central member expands (Column 1, Lines 47-64, Column 4, Lines 16-30, and Column 3, Lines 46-51, and Column 7, Lines 23-30).

Regarding the newly amended claims, Examiner considers the "deployment of the proximal anchor" not being performed until the proximal anchor is completely expanding. Tension is applied prior to the proximal anchor being completely expanded.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Mark Mashack/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773